

United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/066,782	02/06/2002	Gary L. Griffiths	018733-1089 5555	
35857 7590 02/26/2007 RAFAEL LUIS SANTOS 8735 SW 152ND AVE #294 MIAMI, FL 33193			EXAMINER FETTEROLF, BRANDON J	
			ART UNIT	PAPER NUMBER
		1642		
·				
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		02/26/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

	Application No.	Applicant(s)			
	10/066,782	GRIFFITHS ET AL.			
Office Action Summary	Examiner	Art Unit			
	Brandon J. Fetterolf, PhD	1642			
The MAILING DATE of this communication app	ears on the cover sheet with the c	orrespondence address			
Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this common. - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be timulated and will expire SIX (6) MONTHS from a cause the application to become ABANDONE!	I. lely filed the mailing date of this communication. D (35 U.S.C. § 133).			
Status					
Responsive to communication(s) filed on <u>27 No.</u> This action is FINAL . 2b)⊠ This Since this application is in condition for allowar closed in accordance with the practice under E	action is non-final. nce except for formal matters, pro				
Disposition of Claims					
4) Claim(s) 1-14,48 and 49 is/are pending in the a 4a) Of the above claim(s) is/are withdraw 5) Claim(s) is/are allowed. 6) Claim(s) 1-14 and 48-49 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or	wn from consideration.				
Application Papers					
9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) accomplicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the Examine	epted or b) objected to by the bedrawing(s) be held in abeyance. See ion is required if the drawing(s) is obj	e 37 CFR 1.85(a). lected to. See 37 CFR 1.121(d).			
Priority under 35 U.S.C. § 119					
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 					
Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:	ate			

Application/Control Number: 10/066,782

Art Unit: 1642

Response to the Amendment

The Amendment filed on 11/27/2006 in response to the previous Non-Final Office Action (9/21/2006) is acknowledged and has been entered.

Claims 1-14 and 48-49 are currently pending and under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

New Rejections Upon Further Consideration:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-14 and 48-49 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: (1) administration of a bispecific antibody or antibody thereof, wherein one arm of the bispecific antibody is targeted against a target site antigen and a second arm is targeted against a low molecular weight hapten that is conjugated to said enzyme; and (2) administration of a low molecular weight hapten that is conjugated to an enzyme.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

Art Unit: 1642

F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 4-5 and 11 are rejected on the ground of nonstatutory obviousness double patenting as being unpatentable over claims 1, 4-5, 16-18 and 24-25 of US Patent 6,962,702.

Although the conflicting claims are not identical, they are not patentably distinct from each other because a species anticipates a genus. The species method of treating or identifying a diseased tissue in a subject, comprising: (A) administering to said subject a bi-specific antibody or antibody fragment having at least one arm that binds to a tumor and at least one other arm that specifically binds a targetable conjugate comprising at least two HSG haptens, wherein said at least one other arm that specifically binds a targetable conjugate comprising at least two HSG haptens comprises one or more CDRS of MN-14; (B) optionally, administering to said subject a clearing composition, and allowing said composition to clear non-localized antibodies or antibody fragments from circulation; (c) administering to said subject a targetable conjugate which comprises a carrier portion which comprises or bears at least two HSG haptens chemically bound to an enzyme; and (D) further administering to said subject a prodrug such as CPT-11 that is capable of being converted to a toxic drug at the target site by an the enzyme claimed in the conflicting patent appears to fall within the same scope of the genus method of increasing the target specific toxicity of a drug, comprising pretargeting an enzyme to a mammalian target site using a bispecific antibody or fragment, wherein one arm of the bispecific antibody is targeted against a target site antigen and a second arm is targeted against a low molecular weight hapten that is conjugated to said enzyme; and administering a cytotoxic chemotherapeutic agent or prodrug for thereof which is converted to the chemotherapeutic drug in situ claimed in the instant application.

Therefore, NO claim is allowed

Application/Control Number: 10/066,782

Art Unit: 1642

Page 4

All other rejections and/or objections are withdrawn in view of applicant's amendments and arguments there to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J. Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached on Monday through Friday from 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brandon J Fetterolf, PhD Patent Examiner Art Unit 1642

Sanden Fother J. M.

BF